SEP 21 2012

# 510(K) SUMMARY k 112958

## 1. SUBMITTER:

TELEFLEX MEDICAL
INMED MFG.SDN.BHD, RUSCH
P.O. Box 28, Kamunting
Industrial Estate, Kamunting
Perak, Malaysia 34600
Telephone# 605-891-5111
Establishment Registration Number: 8040412

Official contact: Elizabeth Paul, Director, International/Domestic RA
Telephone: 919-433-8076
Date Prepared: September 23, 2011

## 2. DEVICE:

Tradename: Humid-Vent® HEPA
Classification Name: Filter, Bacterial, Breathing-Circuit
Classification: Class II
Common Name: Breathing circuit bacterial filter
Classification Panel: Anesthesiology
Product Code: CAH
Regulation Number: 868.5260

## 3. PREDICATE DEVICES:

- Teleflex Medical's Gibeck Iso-Gard Angled and Straight Filters,
- Teleflex Medical's Gibeck Humid-Vent 2 HME, and
- Covidien's Hygroster Filter / HME combination bacterial / viral filter (HEPA) and heat / moisture exchanger (HME)

## 4. DEVICE DESCRIPTION:

The Humid-Vent® HEPA is a combined Heat and Moisture Exchanger (HME) and a mechanical Bacterial/Viral Filter. The device is used for humidification and bacterial/viral filtration during anesthesia and ventilator care. The device consists of a housing which incorporates a hydrophobic glass fibre filter and an HME media made of corrugated hygroscopic paper. It contains ISO Standard 15M / 22F conical connectors at the machine end as well as the patient end.

## 5. INDICATIONS FOR USE:

The Humid-Vent HEPA Filters are used for humidification and bacterial/viral filtration during anesthesia and ventilator care.

## 6. COMPARISON OF CHARACTERISTICS:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics and packaging are identical or substantially equivalent to the currently marketed predicate devices.

## 7. PERFORMANCE DATA:

The Humid-Vent® HEPA was subjected to a full battery of performance testing including pre-determined acceptance criteria. As expected, the device met all acceptance criteria. The performance data verified that the Humid-Vent® HEPA is substantially equivalent to the currently marketed predicate devices, adequately meets its intended use, and is acceptable for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Teleflex Medical
Ms. Elizabeth Paul
Director, International/Domestic Regulatory Affairs
2917 Weck Drive
Research Triangle Park, North Carolina 27709

SEP 21 2012

Re: K112958
Trade/Device Name: Humid-Vent® HEPA
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: September 18, 2012
Received: September 19, 2012

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K112958

Device Name: Gibeck Humid-Vent® HEPA

Indications for Use:

The Humid-Vent HEPA Filters are used for humidification and bacterial/viral filtration during anesthesia and ventilator care.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112958